



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/786,445

02/25/2004

Rodney A. Welch

096429-9141

5346

23510

7590

06/13/2006

MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

SAIDHA, TEKCHAND

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/786,445	Applicant(s) WELCH ET AL.	
	Examiner Tekchand Saidha	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-16 are pending in the application.
2. Information disclosure Statements (IDS) filed on 7.16.2004 & 7.11.2005 are acknowledged.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1, drawn to a purified antibody that specifically binds to a polypeptide comprising amino acids residues 24-886 of SEQ ID NO: 2, classified in class 530, subclass 387.1.
 - II. Claim 2 (in-part), drawn to a method of reducing colonization of epithelial cells by StcE producing bacteria comprising contacting the epithelial cells with the antibody of claim 1, classified in class 435, subclass 7.2.
 - III. Claim 2 (in-part), drawn to a method of reducing colonization of epithelial cells by StcE producing bacteria comprising contacting the epithelial cells with an inhibitor of StcE, classified in class 435, subclass 69.2.
 - IV. Claims 3-4, drawn to polypeptide composition comprising at least 25 consecutive amino acid residues of SEQ ID NO: 2, classified in class 514, subclass 12.
 - V. Claims 5-6, drawn to a method of eliciting an immune response in an animal comprising inoculating the animal with the composition comprising at least 25 consecutive amino acid residues of SEQ ID NO: 2 or

polypeptide comprising amino acids residues 24-886 of SEQ ID NO: 2, classified in class 514, subclass 12.

- VI. Claims 9-11, drawn to method of reducing the viscosity of a material comprising a mucin or a glycosylated polypeptide comprising contacting the material with a viscosity reducing effective amount of StcE, classified in class 435, subclass 4.
 - VII. Claims 12-13, drawn to a composition for enhancing delivery of a target antigen to mucosal cells comprising the target antigen and StcE, classified in class 424, subclass 94.1.
 - VIII. Claim 14, drawn to a method of detecting StcE in a sample comprising contacting the sample with the antibody of claim 1.
 - IX. Claim 15, drawn to a method of detecting StcE in a sample comprising contacting the sample with Cl-INH under conditions to allow cleavage of Cl-INH by StcE.
 - X. Claim 16, drawn to a method of evaluating a test substance for the ability to inhibit StcE.
 - XI. Claims 7-8, drawn to a method of reducing complement-mediated disruption of cells comprising contacting the cells with a purified polypeptide comprising SEQ ID NO: 2 or 19, classified in class 435, subclass 4.
4. The inventions are distinct, each from the other because of the following reasons:
5. The proteins of Invention III are related to the antibodies of Invention I by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct Inventions because the protein can

Art Unit: 1652

be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

6. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP . 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for the detection of StcE protein.

7. Inventions I and VIII or VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP . 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for the colonization of epithelial cells by StcE producing bacteria.

8. The methods of Inventions IV, V, VI, IX, XI and XI are related in that each method requires the use of I or III or VII. However, the steps and end points of the methods are wholly different and therefore Inventions IV, V, VI, IX, XI and XI are patentably distinct.

Art Unit: 1652

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Applicants are advised that the reply to this requirement MUST include an election of the invention to be examined, even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tekchand Saidha
Primary Examiner, Art Unit 1652
Recombinant Enzymes, E03A61 Remsen Bld.
400 Dulany Street, Alexandria, VA 22314
Telephone : (571) 272-0940

June 5, 2006